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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/626,633 | 07/25/2003 | Gianni Guala | Q75566 | 9622 |
| 7590 | 03/07/2006 | | EXAMINER | |
| SUGHRUE, MION , ZINN, MACPEAK & SEAS, PLLC 2100 Pennsylvania Avenue, N.W. Washington, DC 20037-3202 | | | | DEAK, LESLIE R |
| | | ART UNIT | PAPER NUMBER | 3761 |

DATE MAILED: 03/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|------------------------|---------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/626,633 | GUALA, GIANNI |
| | Examiner | Art Unit |
| | Leslie R. Deak | 3761 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 16 December 2005.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 10-12 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 10-12 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 25 July 2003 is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 11 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 11 recites the limitations that the cap "is formed externally" with manual actuation parts. It is unclear whether applicant is claiming a method of forming a device or an additional structural limitation. Examiner has interpreted the claim to refer to a structural limitation. However, "formed externally" is unclear, and examiner is not sure what structure that limitation encompasses. Examiner has interpreted the claim to encompass a cap that has external ribs.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 10, 11 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,360,404 to Novacek et al.

Novacek, in the specification and figures, discloses the invention as claimed by applicant. In particular, Novacek discloses a needle assembly 18 with a needle guard or

cap 20, hollow body hub 22, a Luer adapter 24 for receiving needle hub 22 (the illustrated embodiment shows a Luer fit, but Novacek specifically discloses that the connection may comprise a Luer lock or a Luer fit—see column 7, lines 40-60), and a needle 21 (see FIGS 1-7, column 5, lines 30-50). The cap, which comprises manual actuation parts 100 (claims 8, 9) is removably placed over the needle to enclose the needle (see FIG 7) and comprises teeth or ribs 142 that cooperate with teeth or ribs on the needle hub 140.

The sawtooth-shaped ribs are arranged such that when one provides rotational torque to remove the needle hub from a connector, the cap stays on the hub. Similarly, if one rotates the cap to remove it from the needle, the hub remains attached to the connector. The sawtooth-shaped ribs are interpreted by the examiner to be “axially tapered” since they taper in the direction perpendicular to the plane of the circular structure (see Merriam-Webster’s Collegiate Dictionary, 10th ed., 2001).

With regard to applicant’s claims drawn to the rotation and coupling of the hub and the cap, such limitations amount to a statement of the intended use of the device. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. See MPEP 2114. Since the previously disclosed apparatus is capable of performing in the manner claimed, the instant invention is not patentable over the Novacek reference.

With regard to claims 11 and 12, Novacek discloses that the cap may encompass ribs on the surface of the cap (see FIG 32) and that the cap features an annular flange (unlabeled, see flange between parts 22e and 169 in FIG 35).

Response to Arguments

5. Applicant's amendment filed 16 December 2005 has been entered and considered.
6. Applicant's amendment rendered moot the 35 U.S.C. § 112 rejection of claims 1-10, but a new rejection has been made on the new claims.
7. Applicant's arguments filed 16 December 2005 have been fully considered but they are not persuasive.
8. In response to applicant's argument that the instantly claimed cannula and cap combination does not function in the way disclosed by Novacek, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. The sawtooth-shaped ribs disclosed by Novacek are interpreted by the examiner to be "axially tapered" since they taper in the direction perpendicular to the plane of the circular structure (see Merriam-Webster's Collegiate Dictionary, 10th ed., 2001).

Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

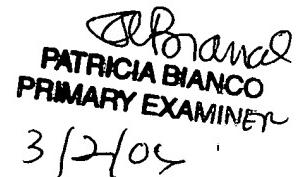
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie R. Deak whose telephone number is 571-272-4943. The examiner can normally be reached on M-F 7:30-5:00, every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Leslie R. Deak
Patent Examiner
Art Unit 3761
27 February 2006



DeBrand
PATRICIA BIANCO
PRIMARY EXAMINER
3/2/06